

# ROMÂNIA

## Immedica Methodology Note

**EFPIA Transparency/ARPIM public reporting of transfers of value in Romania**

## 1. Background

Transparency is fundamental to ensure a positive working relationship between the pharmaceutical industry and healthcare providers, relationships that best serve the interests of patients. Immedica Pharma AB and its affiliates, including the Immedica Specialty Care RO S.R.L. is therefore committed to meet all global transparency requirements, including the EFPIA Disclosure Code in Europe. The code places a requirement on pharmaceutical companies to publicly report payments (transfers of value) made to health care professionals (HCP) and health care organization (HCO).

The methodology note is also a summary describing the methods used by Immedica Pharma AB and its affiliates, including the Immedica Specialty Care RO S.R.L. during the collection and publication of transfers of value (ToV) to HCPs and HCOs. According to the instruction from The Romanian Association of International Medicine Manufacturers, ARPIM, EFPIA affiliate in Romania, such a note shall be published together with the annual report of transfers of value.

The reason for publishing a methodology note is so external recipients of the annual report may fully benefit from an informed reading of the report by understanding how data has been collected. Immedica Specialty Care RO S.R.L. and Immedica Pharma AB follows the local trade association instructions for disclosing ToVs provided in the local industry codes. Furthermore, the ARPIM Code on Disclosure of Transfers of Value from Pharmaceutical Companies to Healthcare Professionals (HCP) and Healthcare Organisations (HCO) ("ARPIM HCO/HCP Disclosure Code") is used as guideline for how disclosure should be conducted. However, there are some details which trade associations and ARPIM leave to the individual companies to decide on. This note is primarily intended to answer those questions.

The information in the methodology note corresponds to instructions provided to Immedica Specialty Care RO S.R.L. and Immedica Pharma AB employees involved in the collection and reporting of transfers of value.

## 2. Methodology

### 2.1 General

#### ***What is included in the annual report?***

Transfers of value (ToV) made by the Immedica Specialty Care RO S.R.L. and Immedica Pharma AB to Health Care Professionals (HCPs) and Health Care Organizations (HCOs) with their primary practice in Romania.

#### ***What is a Transfer of Value (ToV)?***

A ToV can be salary, fee or remuneration for a service provided by the HCP or HCO to Immedica Specialty Care RO S.R.L. and Immedica Pharma AB. Expenses incurred during the execution of the service (e.g. travel and accommodation) are also considered ToV. Donations and sponsorships provided by Immedica Specialty Care RO S.R.L. and Immedica Pharma AB are also considered to be ToV.

#### ***Which ToVs are not included in the Immedica Specialty Care RO S.R.L. and Immedica Pharma AB report?***

Immedica Specialty Care RO S.R.L. and Immedica Pharma AB has decided to comply with the instructions provided by the local trade associations and ARPIM. ToVs to recipients other than those mentioned in these instructions will not be reported in this report.

#### ***Who is the recipient of the transfer of value?***

Immedica Specialty Care RO S.R.L. and Immedica Pharma AB will mostly consider the recipient to be the contracting entity, which may be a HCP, a legal entity owned by a HCP (which is then a HCO) or a HCO, or it may be also ultimate beneficiary of transferred values, if contract is concluded with third party (for example Professional Event Organizer "PCO"). Hence the contracting party as stated on the legal contract drafted between Immedica Specialty Care RO S.R.L. and Immedica Pharma AB

and the counterpart or ultimate beneficiary of transferred values, will be reported as the recipient.

***When are Transfers of Value (ToV) disclosed?***

ToV made by Immedica Specialty Care RO S.R.L. and Immedica Pharma AB during a calendar year are reported within six (6) months from the end of that calendar year. ToVs are handled according to the cash basis principle, hence a specific ToV is registered when the payment is made. As a consequence, a fee for a service provided during 2022 and paid during 2023 will be registered on the 2023 ToV listing. If the exact date for a specific transfer cannot be obtained by the individuals registering the ToVs, the transfer is to be registered as close as possible to the actual payment date.

***Where (i.e. in which country) is a ToV disclosed?***

Immedica Specialty Care RO S.R.L. and Immedica Pharma AB will produce one report per country which is in scope of the ARPIM HCO/HCP Disclosure Code. Each report will be published locally according to the instructions provided by each ARPIM member association (i.e. local trade association) as well as on the Immedica Pharma AB external webpage ([www.immedica.com](http://www.immedica.com)). A specific ToV will be disclosed in the country report where the HCP has his/her primary practice or where the HCO is registered.

***Where are R&D transfer of value (ToV) disclosed?***

A majority of R&D ToV will be paid by the Immedica Pharma AB to recipients in many European countries. Immedica Pharma AB will disclose such aggregate ToV in the country where the recipient has its primary practice. Hence R&D ToV to a Romanian recipient will be reported in Romania.

***Is value added tax (VAT) included in the reported amounts?***

- Fee for service (natural person providing services) – not applicable.
- Fee for service (legal entity providing services - fee excluding VAT disclosed).
- Out of pocket expenses – the entire expense is disclosed (i.e. including VAT paid by the service provider).
- Travel and accommodation costs – cost including VAT is disclosed.
- Registration fees (congresses) – cost including VAT is disclosed.
- Other transfers of value (e.g. donations, grants and sponsorships) - the cost excluding applicable VAT is disclosed.

If a HCP/HCO does not attend a meeting which has already been paid for, an actual transfer of value has not taken place. Hence such costs will not be registered/disclosed as a Transfer of Value.

***How are the reported value of charitable product donations provided by Immedica Specialty Care RO S.R.L. and Immedica Pharma AB determined?***

In such cases the local market value is used for reporting purposes.

## 2.2 Data Privacy and Consent

***How is Immedica Specialty Care RO S.R.L. and Immedica Pharma AB handling HCPs and HCOs data?***

Immedica Specialty Care RO S.R.L. and Immedica Pharma AB is committed to protect the personal rights of any individual whose Personal Data it processes. All processing of Personal Data subject to the provisions in the EU General Data Protection Regulation (GDPR) must fully comply with the GDPR. In order to fulfil these requirements Immedica Specialty Care RO S.R.L. and

Immedica Pharma AB must ask the relevant recipients of ToV (i.e. HCPs and in some exceptional cases HCOs) for a signed informed consent to publicly disclose the ToV. HCPs has the right to access the personal data that Immedica Specialty Care RO S.R.L. and Immedica Pharma AB processes concerning the HCP and to request that Immedica Specialty Care RO S.R.L. and Immedica Pharma AB rectifies any inaccurate personal data and under certain circumstances request erasure and/or restriction of processing of the personal data. HCPs has the right to object to processing and to receive the processed personal data in a structured, commonly used and machine-readable format and has the right to transmit those data to another controller.

***How will Immedica Specialty Care RO S.R.L. and Immedica Pharma AB handle ToVs subject to individual disclosure to a recipient who does not provide consent to disclosure of his/her name?***

In order to contribute to the EFPIA disclosure code purpose, Immedica Specialty Care RO S.R.L. and Immedica Pharma AB aims at disclosing ToVs on an individual basis (stating the name of the recipient) to the greatest extent possible when so required by the EFPIA disclosure code. There are, however, circumstances which require Immedica Specialty Care RO S.R.L. and Immedica Pharma AB to disclose ToVs in aggregate. Under the European privacy legislation, HCPs may oppose to the disclosure of their personal data. If a HCP opposes to such disclosure Immedica Specialty Care RO S.R.L. and Immedica Pharma AB will report such ToVs in aggregate (stating the ToV amount to a group of recipients without stating the name of the recipients). Such aggregate disclosures will be reported under "Other" in the report template.

***How will Immedica Specialty Care RO S.R.L. and Immedica Pharma AB handle partial consents, i.e. if a HCP agrees to the disclosure of one ToV but opposes disclosure of other ToVs?***

If an individual provides partial consent (i.e. consent to disclosure of some transfers of value but not to others made during the same calendar year) Immedica Specialty Care RO S.R.L. and Immedica Pharma AB will treat all transfers of value to that individual in the same way and will report all transfers of value in aggregate under "Other" in the annual report.

***How will Immedica Specialty Care RO S.R.L. and Immedica Pharma AB handle different consent input from a recipient regarding a ToV, i.e. both consent provided and consent declined?***

In the event that a recipient provides several different consent inputs regarding a given ToV, the latest received input will be considered when deciding on individual or aggregate disclosure of that ToV.

***How will Immedica Specialty Care RO S.R.L. and Immedica Pharma AB handle Transfers of Value (ToV) which may pertain to commercially sensitive data or other information not suitable for disclosure?***

If such data falls within the scope of EFPIA disclosure code, Immedica Specialty Care RO S.R.L. and Immedica Pharma AB will report such ToV in aggregate.

## 2.3 Recipients

***Which recipients are in scope for the disclosure in Romania?***

HCPs and HCOs with their primary practice in Romania.

***What about academic institutions and similar organisations: should Transfers of Value (ToV) to such organisations included in the Specialty Care RO S.R.L. and Immedica Pharma AB report?***

In general, Immedica Specialty Care RO S.R.L. and Immedica Pharma AB will not include ToVs to academic institutions in the annual report. However, if the ToV benefits an identified/identifiable HCP or HCO, Immedica Specialty Care RO S.R.L. and Immedica Pharma AB will include the ToV. Hence a ToV made to a Faculty of Medicine at a university or to a University hospital should normally be included.

***What about CROs (contractual research organisations), are ToVs to them included in the Immedica Specialty Care RO S.R.L. and Immedica Pharma AB report?***

No.

**What about payments made from Immedica Specialty Care RO S.R.L. and Immedica Pharma AB to HCOs/HCPs through CRO's, are they included in the Immedica Specialty Care RO S.R.L. and Immedica Pharma AB report?**

Yes, all direct and indirect ToVs to HCPs and HCOs are included in the Immedica Specialty Care RO S.R.L. and Immedica Pharma AB report.

**What about ToVs to a "Foundation", are they included in the Immedica Specialty Care RO S.R.L. and Immedica Pharma AB report?**

This will be determined by Immedica Specialty Care RO S.R.L. and Immedica Pharma AB on a case-by-case basis. If the foundation is a legal entity through which HCPs/HCOs operate, then the ToV will be included in the report.

## 2.4 Fee of service and consultancy

**Examples of Transfers of Value that could be covered under Fee for Service and Consultancy agreements**

- Speakers' fees.
- Speaker training.
- Medical writing.
- Data analysis.
- Development of educational materials.
- General consulting / advising.

### **Market research**

Fees paid for participation in market research are reported only if the recipient is known to Immedica Specialty Care RO S.R.L. and Immedica Pharma AB.

**What is included in the reported salary/fee?**

Fees paid by Immedica Specialty Care RO S.R.L. and Immedica Pharma AB are registered as gross fees, including applicable taxes. Value added tax (VAT) and social security fees, if applicable, are however not included in the reported fees.

### **Related expenses**

Immedica Specialty Care RO S.R.L. and Immedica Pharma AB pays for/reimburses consultants for reasonable and documented expenses regarding travel and accommodation necessary for providing the services to Immedica Specialty Care RO S.R.L. and Immedica Pharma AB. Such reimbursement will be considered as a related expense. Travel and accommodation costs are reported including VAT. Other expenses are normally not paid for/reimbursed by Immedica Specialty Care RO S.R.L. and Immedica Pharma AB. If another type of related expense (excluding travel, accommodation, meals and drinks) are incurred it will be paid for/reimbursed by Immedica Specialty Care RO S.R.L. and Immedica Pharma AB only if it was necessary in order to perform the service. If so, it will be reported in "Related expenses" in the annual report. Such expenses incurred during the performance of the services are reimbursed to the service provider on submission of a receipt. The entire expense is reimbursed, including any VAT.

### **Meals and drinks**

Meals and drinks are not to be reported according to ARPIM and hence will not be reported by Immedica Specialty Care RO S.R.L. and Immedica Pharma AB.

## 2.5 The report template

**What is disclosed under "HCP"?**

HCP is an abbreviation for Health Care Professionals. Transfers of value (i.e. fee for service and related expenses) to individuals included in this category are reported under HCP in the annual report.

**What is disclosed under “HCO”?**

HCO is an abbreviation for Health Care Organisations and include organisations which organises/include HCPs. A HCO is always a legal entity. Fees and related expenses invoiced from a HCO is reported under HCO in the annual report. Donations and sponsorships provided to HCOs are also reported under HCO in the annual report.

**What is disclosed under “Other”?**

ToVs that should be reported in aggregate according to the ARPIM HCO/HCP Disclosure Code or ToVs which Immedica Specialty Care RO S.R.L. and Immedica Pharma AB due to e.g. legal reasons, must disclose in aggregate, are reported under “Other”.

**What is disclosed under R&D?**

ToVs related to the planning or conduct of (i) non-clinical studies (as defined in *OECD Principles on Good Laboratory Practice*); (ii) clinical trials (as defined in Directive 2001/20/EC); or (iii) non-interventional studies that are prospective in nature and that involve the collection of patient data from or on behalf of individual, or groups of HCPs specifically for the study.

A number of activities are regarded as *related* to the planning and conduct of such studies.

Immedica Specialty Care RO S.R.L. and Immedica Pharma AB includes e.g. ToVs related to advisory boards (provided that the advisory board is clearly related to the planning of a study mentioned above), costs for providing study drugs and ToV to study staff for conducting the study.

Immedica Specialty Care RO S.R.L. and Immedica Pharma AB will include ToVs related to Immedica-sponsored studies as well as non-Immedica sponsored studies in the R&D category.

### 3. Contact information

Inquiries about Immedica Specialty Care RO S.R.L. and Immedica Pharma AB disclosure of ToVs to HCPs and HCOs to request further information or corrections by Immedica Specialty Care RO S.R.L. and Immedica Pharma AB should be directed to: Immedica Pharma AB, Solnavägen 3H, 113 63 Stockholm, Sweden, [info@immedica.com](mailto:info@immedica.com), tel.: +46 (0)8 533 39 500.

Details about transparency and disclosure you can find to:

<https://www.immedica.com/transparency-disclosure/> .